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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/867,612	06/02/97	WANG	Y ALX-149

EXAMINER	
GAMBEL, P.	
ART UNIT	**PAPER NUMBER**
1644	12

HM22/0801

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DATE MAILED: 08/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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1- File Copy

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08/867612

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
1644	22

DATE MAILED:

Below is a communication from the EXAMINER in charge of this application

COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

☐ THE PERIOD FOR RESPONSE:

a) ☐ is extended to run _____ or continues to run _____ from the date of the final rejection

b) ☐ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition , and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☑ Appellant's Brief is due in accordance with 37 CFR 1.192(a).

☑ Applicant's response to the final rejection, filed 7/3/01 has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

1. ☐ The proposed amendments to the claim and /or specification will not be entered and the final rejection stands because:

   a. ☐ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.

   b. ☐ They raise new issues that would require further consideration and/or search. (See Note).

   c. ☐ They raise the issue of new matter. (See Note).

   d. ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

   e. ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.

   NOTE: _____

2. ☐ Newly proposed or amended claims _____ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.

3. ☑ Upon the filing an appeal, the proposed amendment ☑ will be entered ☐ will not be entered and the status of the claims will be as follows:

   Claims allowed: _____
   Claims objected to: _____
   Claims rejected: 1-14, 17-18

   Phillip Gambel
   PHILLIP GAMBEL, PH.D 7/3/01
   PRIMARY EXAMINER
   TEL# CENTER 1600

   However;

   ☑ Applicant's response has overcome the following rejection(s): 112, 1ST NEW MATTER, DEPOSIT 112 2ND (A)(B)

4. ☑ The affidavit, exhibit or request for reconsideration has been considered but does not overcome the rejection because FOR THE REASONS OF RECORD. SUFFICIENT MOTIVATION AND EXPECTATION OF SUCCESS IN THE PRIOR ART. 112 2ND MAINTAINED FOR REASONS OF RECORD

5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficent reasons why it was not earlier presented. IN THE ABSENCE OF ATCC ACCESSION NUMBER IN CLAIMS

☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.

☐ Other

PTOL-303 (REV. 5-89)

DETAILED ACTION

1. Applicant's amendment, filed 11/8/00 (Paper No. 35), is acknowledged.
Claims 1, 2, 3, 6, 8, 9, 10, 14 have been amended.

The numbering of claims is not accordance with 37 C.F.R. 1.126. The original numbering of the claims must be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When claims are added, except when presented in accordance with 37 CFR 1.121(b), they must be renumbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 18-19 have been renumbered 17-18.

Claims 17-18 have been added.

Claims 15 and 16 have been canceled previously.

Claims 1-14 and 17-18 are pending and being acted upon presently.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.
This Office Action will be in response to applicant's arguments, filed 11/8/00 (Paper No. 35).
The rejections of record can be found in the previous Office Action (Paper No. 21).

3. Again, applicant should amend the first line of the specification to update the status of the priority application, which is now abandoned.

4. Upon reconsideration of applicant's amended claims, filed 11/8/00 (Paper No. 35); the previous rejection under 35 U.S.C. § 112, first paragraph, written description with respect to the recitation of "does not interfere with cellular immune responses seen after immunizing mice with bovine type II collagen" has been withdrawn.

5. Claims 1-14 and 17-18 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. The specification as originally filed does not provide support for the invention as now claimed: "composition comprising at least one purified antibody specific against C5".

Applicant's amendment, filed 11/8/00 (Paper No. 35), directs support to page 29, lines 14-21 of the specification for the written description for the above-mentioned "limitation".

However, the disclosure of anti-C5 antibodies as C5 blockers does not provide sufficient written description for "at least one purified antibody specific against C5".

In contrast, the instant claims appear to set forth a new subgenus by reciting "at least one purified antibody specific against C5"; wherein the intent would be a composition comprising a mixture of different anti-C5 antibodies, that is antibodies that bind distinct C5 epitopes.

In addition, there appears to be no range or upper limit to the recitation of "at least one", particularly in the context of anti-C5 antibodies with different epitope specificities.

Applicant's reliance on generic disclosure and possibly a single species does not provide sufficient direction and guidance to the "claimed limitations" having the features currently claimed

It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. In re Smith 173 USPQ 679, 683 (CCPA 1972). See MPEP 2163.05(b).

The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Applicant is claiming a subgenus not supported by the specification as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office action

Alternatively, applicant is invited to provide sufficient written support for the "limitation" indicated above.

6. Upon reconsideration of applicant's amended claims, filed 11/8/00 (Paper No. 35); the previous rejection under 35 U.S.C. § 112, first paragraph, enablement with respect to "C5 blockers" has been withdrawn.

7. Claim 18: It is apparent that the 5G1.1 antibody is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the cell line / hybridoma which produces this antibody. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

8. Upon reconsideration of applicant's amended claims, filed 11/8/00 (Paper No. 35); the previous rejection under 35 U.S.C. § 112, first paragraph, enablement with respect to "C5 blockers" has been withdrawn.

9. Claims 1-14 and 17-18 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1-14 and 17-18 are indefinite in "composition comprising at least one purified antibody specific against C5" because the metes and bounds of this limitation is not clear.

For example, it is not clear that the intent of the claimed recitation reads on methods which employ a composition comprising a mixture of different anti-C5 antibodies, that is antibodies that bind distinct C5 epitopes.

In addition, there appears to be no range or upper limit to the recitation of "at least one", particularly in the context of anti-C5 antibodies with different epitope specificities

B) The recitation of "C5 blocker" in claims 2-14 and 17-18 lacks proper antecedent basis.

C) Claim 18 is indefinite in the recitation of "5G1.1" because its characteristics are not known. The use of "5G1.1" monoclonal antibody as the sole means of identifying the claimed antibody renders the claim indefinite because "5G1.1" is merely a laboratory designation which does not clearly define the claimed product, since different laboratories may use the same laboratory designation to define completely distinct hybridomas / cell lines .

D) Applicant should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06

10. Upon reconsideration of applicant's amended claims, filed 11/8/00 (Paper No. 35); the previous rejection under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Sindelar et al. (U.S. Patent No. 5,173) have been withdrawn.

11. Claims 1-14 and newly added claim 17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Sindelar et al. (U.S. Patent No. 5,173,499; 1449) in view of Auda et al. (Rheumatol. Int.10: 185-18, 1990; 1449) , Wurzner et al. (Complement Inflamm. 8: 328-340, 1991; 1449) and Montz et al. (Cell. Immunol. 127: 337-351, 1990; 1449) for the reasons of record.

Claims 1-14 and newly added claim 17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Sindelar et al. (U.S. Patent No. 5,173,499; 1449) in view of Auda et al. (Rheumatol. Int.10: 185-18, 1990; 1449) , Wurzner et al. (Complement Inflamm. 8: 328-340, 1991; 1449) and Montz et al. (Cell. Immunol. 127: 337-351, 1990; 1449) as applied to claims 1-17 above and in further evidence of Rollins et al. (U.S. Patent No. 5853,722) for the reasons of record.

Claims 1-14 and newly added claims 17-18 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Sindelar et al. (U.S. Patent No. 5,173,499; 1449) in view of Auda et al. (Rheumatol. Int.10: 185-18, 1990; 1449) , Wurzner et al. (Complement Inflamm. 8: 328-340, 1991; 1449) and Montz et al. (Cell. Immunol. 127: 337-351, 1990; 1449) as applied to claims 1-14 and 17 above
OR
as applied to claims 1-17 above and in further evidence of Rollins et al. (U.S. Patent No. 5853,722) for the reasons of record
either in further view of Wang et al. (U.S. Patent No. 6,074,642

The prior art references of record differ from the claimed methods by disclosing the particular 5G1.1 anti-C5 antibody.

Wang et al. Teach the anti-C5 antibody 5G1.1. which has the properties encompassed by the claimed invention, including its use in treating an inflammatory/autoimmune condition (see entire document, including columns 17-19).

Given the properties of the anti-C5 5G1.1 antibody, including its ability to inhibit an inflammatory or autoimmune condition characterized, to some degree, with immune complexes; the ordinary artisan would have been motivated to substitute the anti-C5 5G1.1. antibody in the instant methods of inhibiting another inflammatory or autoimmune condition with an expectation of success at the time the invention was made.

12. Applicant's arguments, filed 11/8/00 (Paper No. 35), have been fully considered but are not found convincing essentially for the reasons of record.

Applicant argues that Sindelar et al. is directed to chemically synthesized non-protein organic compounds for the inhibition and/or suppression of immune activity and that Sindelar et.al. Does not disclose the use of antibodies.

Applicant argues that Wurzner et al. Does not disclose the use C5-specific antibodies to treat joint inflammatory conditions.

Applicant argues that Montz et al. Is directed toward the role of anti-C5 antibodies in T cell proliferation and not to treating joint inflammation.

Applicant argues that Rollins is improperly applied against the pending claims since the issue date is 12/29/98 and the filing date is 12/2195.

However, the priority date of Rollins et al. Is 3/23/94 and therefore stands as prior art.

In response to applicant's arguments that is nonanalogous art, it has ben held that the prior art reference must either be in the filed of applicant's endeavor or, if not then be reasonably pertinent to the particular problem with which the applicant was concerned in to order to be relied upon as a basis for rejection of the claimed invention. See In re Oetiker 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the combination of prior art references are drawn to the inhibition of complement-mediated activity, including C5-mediated activity, and the inhibition of complement-mediated inflammatory processes, such as arthritis.

Also, it appears that applicant's arguments addressed the references individually. One cannot show non - obviousness by attacking references individually where the rejections are based on combinations of references. In re Keller , 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., Inc. , 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). See MPEP 2145.

Applicant's arguments are not found persuasive.

13. No claim is allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

PHILLIP GAMBEL

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
March 28, 2001